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| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |          |  |                    |  |          |              |      |  |           |               |            |       |
|--|---------------|----------------------|---|------------------|----------|--|--------------------|--|----------|--------------|------|--|-----------|---------------|------------|-------|
| 10/582,946   | 03/02/2007    | Lars-Goran Axelsson  | 514862004000  | 1558             |          |  |                    |  |          |              |      |  |           |               |            |       |
| 7590<br>Lisa A. Haile, Ph.D.<br>DLA Piper US LLP<br>4365 Executive Drive<br>Suite 1100<br>San Diego, CA 92121-2133 |               | 09/14/2007           | <table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">PITRAK, JENNIFER S</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1635</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>09/14/2007</td><td>PAPER</td></tr></table> |                  | EXAMINER |  | PITRAK, JENNIFER S |  | ART UNIT | PAPER NUMBER | 1635 |  | MAIL DATE | DELIVERY MODE | 09/14/2007 | PAPER |
| EXAMINER   |               |                      |   |                  |          |  |                    |  |          |              |      |  |           |               |            |       |
| PITRAK, JENNIFER S   |               |                      |   |                  |          |  |                    |  |          |              |      |  |           |               |            |       |
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| 1635   |               |                      |   |                  |          |  |                    |  |          |              |      |  |           |               |            |       |
| MAIL DATE  | DELIVERY MODE |                      |   |                  |          |  |                    |  |          |              |      |  |           |               |            |       |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/582,946

Applicant(s)

AXELSSON ET AL.

Examiner

Jennifer Pitrak

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-27, drawn to an siRNA molecule directed to a p65 subunit of NF-kappa-B and expression vectors encoding the siRNA molecule.

Group II, claim(s) 28-31, drawn to methods of preventing, treating, or alleviating NF-kappa-B-dependent conditions in an individual.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature, an siRNA to NF-kappa-B, does not make a contribution over the prior art as siRNA to NF-kappa-B is disclosed in Laderach, *et al.* (2003, J. Immun., v.171:1750-1757).

### ***Sequences***

Restriction is required under 35 U.S.C. 121 and 372, because claims 1, 2, and 6-8 specifically claim numerous SEQ ID NOS.

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This international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

- (A) all alternatives have a common property or activity and
- (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The instant sequences are considered to be each separate invention for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. The sequences each behave in a different way in the context of the claimed invention. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved.

Further, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, and a common core structure. Accordingly, unity of invention between the antisense sequences

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is lacking and each sequence claimed is considered to constitute a special technical feature.

**Applicants are directed to elect a single sequence or a single pair of complementary sequences for examination.**

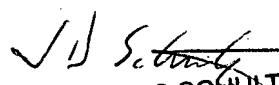
*Closing*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Pitrak whose telephone number is 571-270-3061. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak  
Patent Examiner  
AU 1635

  
J. DOUGLAS SCHULTZ, PH.D.  
SUPERVISORY PATENT EXAMINER